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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,828	11/30/2000	Fabien Schweighoffer	50146/004002	9055

7590

03/25/2003

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,828

Applicant(s)

SCHWEIGHOFFER ET AL.

Examiner

Jeffrey Siew

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-92 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 60-92 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 60-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,251,590 in view of Chee et al (US 5,837,832 Nov. 17, 1998).

Claims 60-92 are drawn to product arrays of nucleic acids to exon or introns or exon-exon, intron intron junction in which the nucleic acids are formed by hybridizing RNA from a sample wherein in at least sequence is partially known with cDNA from a second sample and identifying from hybrids the unpaired regions from differential splicing.

Claims 1-25 to specific sequences on biological chips.

Chee et al teach oligonucleotide probes for detecting sequences that are identical to or different from specific reference sequence (see whole document esp. abstract). They teach probes to CFTR 10 exon (see Figure 7).

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One of ordinary skill in the art would have been motivated to combine the array technology of Chee et al with the method of claims of US6,251,590 in order to identify the multiple nucleic acid sequences that exhibited differential splicing. It would have been prima facie obvious to apply nucleic acids of unpaired regions in Chee et al's array for high throughput capture and detection.

The response states that a terminal disclaimer will be filed upon finding of allowable subject matter. At this time no such finding has been made, the double patenting rejections are maintained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The product claims 72-90 are drawn to nucleic acids which retain or spliced in cell treated reference material. Claims 90-93 are drawn to nucleic acids that hybridize to spliced sequences. The specification discloses methods of obtaining nucleic acids

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that corresponded to spliced regions. The product claims however recite a broad and widely varying genus, the examiner must evaluate any necessary common attributes or features.

Although the specification has a working example Grb2 gene spliced forms, the specification proposes to discover other members of the genus by using the qualitative screening method

There is no description of all the possible varying spliced exon, introns and junctions. The general knowledge in the art concerning spliced variants does not provide any indication of how the structure of one spliced variant within a single gene would be representative across all genes in all organisms. The nature of spliced genes is that they are variant structures and the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. The mere recitation of exon, intron or junctions of spliced variants is not provide the requisite level of description. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only minimal number of this genus is not representative of the variants of the genus and is sufficient to support the claim.

The response filed 1/6/03 has been fully considered and deemed not persuasive. The response states that introns share common attributes and describes cis and trans elements. The common attributes that the response refers to describe generic attributes occur in splicings as described in the art. Such a bland and generic description does not provide enough support for which the 112 first paragraph rejection is based i.e.

a written description of the invention, and of the manner and process of making and using it, in such **full**, clear, concise, and **exact terms** as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

The generic descriptions that many splicing may possess does not provide description as to what the inventors claim they were in possession. For example, a claim to certain scope of mRNAs would not have support based on the fact that it was well known in the art that full transcript mRNAs possess a poly A tail. Such a description would be so general and would go against the basis of 112 first paragraph statute which requires adequate support so as to describe in full, clear and exact terms to one of ordinary skill in the art the invention that is claimed. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only minimal number of this genus with general descriptions from the prior art would not be representative of the variants of the genus and is insufficient to support the claim.

Second, the response states that specification teaches spliced regions and broad methods of obtaining such nucleic acids. The response is reminded that the claims are drawn to a product. The method of obtaining such spliced variants does not necessarily provide written description for such products thereby obtained. While the method of obtaining the spliced variants may be well described, it does not extend the method of fishing for such splices would then adequately support such a wide range products.

Third, the response states that specification teaches products comprising such nucleic acids as presently claimed. The response cites example 3 where libraries of spliced nucleic acids are produced and deposited on supports and example 4 which illustrate the cloned nucleic acids on supports. The specification appears to provided limited examples which do not support the broad scope of the claims. Moreover, the examples describe limitations to the support whereas the heart of the written description rejection is drawn to the nucleic acids. The generic

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descriptions of support and functional language do not provide support for such a broad scope of the claims. The rejections are maintained.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 60-63 & 72-90 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 60-63 & 72-90 are indefinite. It is unclear as to what properties the nucleic acids are to possess other than hybridization to exon or intron or junctions. It is unclear as to limitation the language treatment by reference toxic compound would impart on a product claim. Applicant is reminded that the claims are drawn to product claims. While the claims recite method like steps of obtaining such nucleic acids, it is unclear as to what properties such nucleic acids would possess. It is unclear what would distinguish from the art from other prior art methods of construction.

The amendment to claims to overcome the 112 second paragraph rejection has been considered and deemed not persuasive. While the term cDNA and single stranded oligonucleotides may eliminate certain species of nucleic acids, the phrase still does not clarify the physical or functional limitations of the product which are deemed critical in defining the applicant's invention.

SUMMARY

5. No claims allowed.

CONCLUSION

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.


Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official

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Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.


JEFFREY SIEW
PRIMARY EXAMINER

March 23, 2003